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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	Art Unit: 1614
Esmond *et al.*	Examiner: Kim, V.
Appl. No. 09/394,712	Atty. Docket: 0609.4440002/RWE
Filed: September 13, 1999	
For: **Method for Treating or Preventing Alzheimer's Disease**	**Batch No. A22**

Request For Interference Under 37 C.F.R. § 1.607(a)

Commissioner for Patents
Washington, D.C. 20231

Art Unit 1614

Sir:

This is a request for interference between the captioned application and an issued United States patent.

I. 37 C.F.R. § 1.607(a)(1) - The Identified Patent

It is respectfully requested that an interference be declared under 37 C.F.R. § 1.607(a) between the captioned application and U.S. Patent No. 6,191,154 entitled "Compositions and Methods for the Treatment of Alzheimer's Disease, Central Nervous System Injury, and Inflammatory Diseases" ("the '521 patent," Attachment 1).

The '154 patent issued from application no. 09/200,700, filed November 27, 1998.

The captioned application is a continuation of International Application no. PCT/US98/04731 filed March 12, 1998 (abandoned), which claims the benefit of U.S. Provisional Application No. 60/039,607, filed March 12, 1997. The allowed claims in the captioned application are entitled to a priority date of March 12, 1997. Thus, Applicants have a date of priority which is more that 20 months before the date of priority of the '154 patent.

II. 37 C.F.R. § 1.607(a)(2) - The Proposed Count

Applicants propose the following count:

A method for treating Alzheimer's disease, comprising administering a therapeutically effective amount of at least one PPARγ agonist to a subject, wherein said PPARγ agonist is selected from the group consisting of troglitazone, ciglitazone, pioglitazone, BRL 49653 and englitazone.

or

A method for the treatment of Alzheimer's disease, in a human, comprising administering to the human in need thereof an effective amount of a thiazolidinedione which increases the insulin sensitivity of the human.

III. 37 C.F.R. § 1.607(a)(3) - At Least One Claim in the '154 Patent Corresponds to the Proposed Count

A. Claimed Subject Matter In The '154 Patent

Claims 1-5 of the '154 patent recite:

1. A method for treating Alzheimer's disease, comprising administering a therapeutically effective amount of at least one PPARγ agonist to a subject, wherein said PPARγ agonist is selected from the group consisting of troglitazone, ciglitazone, pioglitazone, BRL 49653 and englitazone.

2. The method of claim 1, wherein said subject is selected from the group consisting of subjects identified as being susceptible to Alzheimer's disease and subjects suffering from Alzheimer's disease.

3. The method of claim 1, wherein said therapeutically effective amount of said PPARγ agonist is between 0.1 mg to 100 mg.

4. The method of claim 1, wherein said therapeutically effective amount of said PPARγ agonist comprises approximately 10 mg/kg per day.

5. The method of claim 1, wherein said administering comprises oral administering.

B. Claims 1-5 of the '154 Patent Correspond to the Proposed Count

Claim 1 of the '154 patent corresponds identically to the first paragraph of the proposed count.

Dependent claim 2 of the '154 patent specifies that the subject is susceptible to Alzheimer's disease or suffering from Alzheimer's disease. Since the only two classes of individuals that would be treated for Alzheimer's disease are those susceptible to Alzheimer's disease or suffering from Alzheimer's disease, claim 2 does not further limit claim 1 and is not patentably distinct from claim 1. Therefore, claim 2 should be designated as corresponding to the proposed count.

Dependent claim 3 of the '154 patent specifies that the therapeutically effective amount of the compound is between 0.1 mg to 100 mg. Since this is a very broad range of dosage, claim 3 is not patentably distinct from claim 1. Therefore, claim 3 should be designated as corresponding to the proposed count.

Dependent claim 4 of the '154 patent specifies that the therapeutically effective amount of the compound comprises approximately 10 mg/kg per day. Since there is no evidence that this dosage imparts any unexpected results in the claimed method, claim 4 is not patentably distinct from claim 1.[1] Therefore, claim 4 should be designated as corresponding to the proposed count.

Dependent claim 5 of the '154 patent specifies that the compound is administered orally. Since troglitazone and pioglitazone are orally active (see Attachment 4, col. 17, lines

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[1]Moreover, Applicants have incorporated by reference U.S. Pat. 5,478,852 (Attachment 4) which describes administration of troglitazone and pioglitazone at preferred dosages of "about 0.01 mg to about 10 mg per kilogram." See col. 17, lines 62-63, for the dosage, col. 14, lines 60-62 for troglitazone, and col. 15, lines 13-14 for pioglitazone.

24-35) and normally administered orally for treatment of type 2 diabetes (see attachments 2 and 3, respectively), claim 5 is not patentably distinct from claim 1. Therefore, claim 5 should be designated as corresponding to the proposed count.

IV. 37 C.F.R. § 1.607(a)(4) - Applicants Identify At Least One Claim In The Captioned Application That Corresponds To The Proposed Count

A. Claimed Subject Matter in the Captioned Application

Claims 7, 21, 22 and 25 of the captioned application recite:

7. The method of claim 25, wherein said thiazolidinedione is troglitazone.

21. The method of claim 25, wherein said thiazolidinedione is 5-[4-[2-(5-ethylpyridin-2-yl)ethoxyl]benzyl]thiadiazolidine-2,4-dione. (pioglitazone)

22. The method of claim 25, wherein said thiazolidinedione is 5-[4-[2-(5-ethylpyridin-2-yl)ethoxyl]benzyl]thiadiazolidine-2,4-dione hydrochloride. (pioglitazone hydrochloride)

25. A method for the treatment of Alzheimer's disease, in a human, comprising administering to the human in need thereof an effective amount of a thiazolidinedione which increases the insulin sensitivity of the human.

B. Claims 7, 21, 22 and 25 of the Captioned Application Correspond to the Proposed Count

Claim 25 is directed to a method for the treatment of Alzheimer's disease, in a human, comprising administering to the human in need thereof an effective amount of a thiazolidinedione which increases the insulin sensitivity of the human. Claim 25 corresponds identically to the second paragraph of the proposed count.

Claim 21 specifies that the thiazolidinedione is 5-[4-[2-(5-ethylpyridin-2-yl)ethoxyl]benzyl]thiadia-zolidine-2,4-dione (pioglitazone, see U.S. Pat. No. 5,478,852 at col.

15, lines 13-14; Attachment 4). Pioglitazone is one of the compounds recited in claim 1 of the '154 patent and in the first paragraph of the proposed count. Therefore, claim 21 should be designated as corresponding to the proposed count.

Claim 22 specifies that the thiazolidinedione is 5-[4-[2-(5-ethylpyridin-2-yl)ethoxyl]benzyl]thiadiazolidine-2,4-dione hydrochloride (pioglitazone hydrochloride). Pioglitazone is one of the compounds recited in claim 1 of the '154 patent and in the first paragraph of the proposed count. Therefore, claim 22 should be designated as corresponding to the proposed count.

Claim 7 specifies that the thiazolidinedione is troglitazone. Troglitazone is one of the compounds recited in claim 1 of the '154 patent and in the first paragraph of the proposed count. Therefore, claim 7 should be designated as corresponding to the proposed count.

V. 37 C.F.R. § 1.607(a)(5) - Application Of The Terms Of Claims 25, 21, 22 and 7 to the Disclosure of the Captioned Application and Provisional Application No. 60/039,607, filed March 12, 1997

Applicants have not copied a claim of the '154 patent. Therefore, Applicants believe that it is not necessary to apply the terms of claims 25, 21, 22 and 7 to the disclosure. However, support for claims 25 and 7 may be found in original claims 1, 6, 7 and 20. Support for the phrase "which increases the insulin sensitivity of the human" recited in claim 25 may be found at page 6, lines 4-6. Support for "5-[4-[2-(5-ethylpyridin-2-yl)ethoxyl]benzyl]thiadiazolidine-2,4-dione" and its hydrochloride salt of claims 21 and 22 may be found on page 7, lines 12, 16 and 19, which cite U.S. Pat. 5,478,852 (see col. 15, lines 13-14 and 46 of the '852 patent, Attachment 4). This patent is incorporated by reference into the application. See page 11, lines 24-25 of the application.

Priority application no. 60/039,607, filed March 12, 1997, is the grandparent of the captioned application. Support for claims 25 and 7 of the captioned application is also found throughout application no. 60/039,607, for example, in claims 1, 9 and 10, and page 5, lines 18-20. Support for "5-[4-[2-(5-ethylpyridin-2-yl)ethoxyl]benzyl]thiadiazolidine-2,4-dione" and its hydrochloride salt of claims 21 and 22 may be found on page 6, lines 22, 26 and 28, which cite U.S. Pat. 5,478,852 (see col. 15, lines 13-14 and 46 of the '852 patent). This patent is incorporated by reference into the application. See page 10, lines 7-8 of the application.

VI. 37 C.F.R. § 1.607(a)(6) - The Requirements of 35 U.S.C. § 135(a) are Met

A claim must be made prior to one year from the date of patent issue. 35 U.S.C. § 135(b). The '154 patent issued on February 20, 2001. Thus, to conform with 35 U.S.C. § 135(a), the date by which a claim must have been present in the captioned application, or an earlier priority application, is February 20, 2002. Since allowed claims 25, 21, 22 and 7 of the captioned application were presented before the '154 patent issued, the requirements of 35 U.S.C. § 135(a) are met.

VII. 37 C.F.R. § 1.608(a) - Applicants are Entitled to Judgment of Priority

The application from which the '154 patent issued was filed on November 27, 1998. The effective filing date of the captioned application is March 12, 1997. Therefore, Applicants are entitled to a judgement of priority.

VIII. Conclusion

As provided above, the requirements of 37 C.F.R. § 1.607(a) have been satisfied. In view of the foregoing, it is respectfully requested that an interference be declared between the captioned application and the '154 patent. Early notice to that effect is earnestly solicited.

If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Respectfully submitted,

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Attachments

1 - U.S. Patent No. 6,191,154

2 -Physician's Desk Reference, Medical Economics Company, Inc., Montvale, NJ, pp.2278-2282 (2000)

3 - Physician's Desk Reference, Medical Economics Company, Inc., Montvale, NJ, pp. 3088-3053 (2000)

4-U.S. Patent No. 5,478,852

P100-75.WPD